IN THE UNITED STATES DISTRICT COURT OF THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

IN RE: DIGITEK PRODUCTS LIABILITY LITIGATION

MDL NO. 1968

MASTER CONSOLIDATED COMPLAINT FOR INDIVIDUALS

I. INTRODUCTION

1. Plaintiffs bring this Master Consolidated Complaint for Individual Plaintiffs for various claims against Defendants and its affiliates related to the marketing, designing, manufacturing, producing, supplying, inadequately inspecting, inadequately testing, selling, and distributing dangerous, defective, misbranded and adulterated Digitek® (Digoxin).

II. PARTIES

A. Plaintiffs

2. This Master Consolidated Complaint for Individual Plaintiffs is brought on behalf of all Plaintiffs, and deceased Plaintiffs ("Decedent Plaintiffs") who were prescribed, purchased and ingested Digitek® (Digoxin), and the Spouse Plaintiffs and/or Family Member Plaintiffs whose spouses and/or family members were prescribed, purchased and ingested Digitek® (Digoxin).

B. Defendants

3. Defendant Actavis Totowa, LLC is a New Jersey corporation organized, existing and conducting business in the State of New Jersey with its principal place of business in Morristown, New Jersey. At all times relevant to this Complaint, Actavis Totowa, LLC was engaged in the business of manufacturing, marketing, testing, promoting, selling and/or distributing Digitek® (Digoxin). At all times relevant herein, Actavis Totowa, LLC regularly

transacted, solicited and conducted business in West Virginia, including the marketing, promoting, testing, selling and/or distribution for the sale of Digitek® (Digoxin).

4. Actavis, Inc. is a Delaware corporation. At all times relevant herein, Actavis, Inc., was engaged in the business of manufacturing, marketing, testing, promoting, selling and/or distributing Digitek® (Digoxin). At all times relevant herein, Actavis, Inc. regularly transacted, solicited and conducted business in West Virginia, including the marketing, promoting, selling and/or distribution for the sale of Digitek® (Digoxin).

5. Actavis Elizabeth, Inc. is a Delaware corporation. At all times relevant herein, Actavis, Inc., was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing Digitek® (Digoxin). At all times relevant herein, Actavis Elizabeth, Inc. regularly transacted, solicited and conducted business in West Virginia, including the marketing, promoting, selling and/or distribution for the sale of Digitek® (Digoxin).

6. Mylan, Inc. is a Pennsylvania corporation with its principal place of business located in New Jersey. At all times relevant herein, Mylan, Inc. was engaged in the business of marketing, promoting, selling and/or distributing Digitek® (Digoxin). At all times relevant herein, Mylan, Inc. regularly transacted, solicited and conducted business in West Virginia, including the marketing, promoting, selling and/or distribution for the sale of Digitek® (Digoxin).

7. Mylan Pharmaceuticals, Inc. is a West Virginia corporation with its principal place of business located in Morgantown, West Virginia. At all times relevant herein, Mylan Pharmaceuticals, Inc. was engaged in the business of marketing, promoting, selling and/or distributing Digitek® (Digoxin). At all times relevant herein, Mylan Pharmaceuticals, Inc.

regularly transacted, solicited and conducted business in West Virginia, including the marketing, promoting, selling and/or distribution for the sale of Digitek® (Digoxin).

8. Mylan Bertek Pharmaceuticals, Inc. is a Texas corporation. At all times relevant herein, Mylan Bertek Pharmaceuticals, Inc. was engaged in the business of manufacturing, marketing, testing, promoting, selling and/or distributing Digitek® (Digoxin). At all times relevant herein, Mylan Bertek Pharmaceuticals, Inc. regularly transacted, solicited and conducted business in West Virginia, including the marketing, promoting, testing, selling and/or distribution for the sale of Digitek® (Digoxin).

9. UDL Laboratories, Inc. is an Illinois corporation. At all times relevant herein, UDL Laboratories, Inc. was engaged in the business of manufacturing, marketing, testing, promoting, selling and/or distributing Digitek® (Digoxin). At all times relevant herein, UDL Laboratories, Inc. regularly transacted, solicited and conducted business in West Virginia, including the marketing, promoting, selling and/or distribution for the sale of Digitek® (Digoxin).

III. JURISDICTION AND VENUE

10. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(a).

11. This complaint is drafted and filed in the Southern District of West Virginia in accordance with Pre-Trial Order #11. Transfer and consolidation for pre-trial purposes of cases in MDL-1968 to this venue is proper under 28 U.S.C. § 1407. Venue for trial purposes is to be determined on a case by case basis.

IV. FACTUAL ALLEGATIONS

A. The Drug - Digitek® (Digoxin)

12. Digitek® is the brand-name of one of the cardiac glycosides, a closely related group of drugs having in common specific effects on the myocardium of the heart.

13. Actavis Group, through its manufacturing division, Actavis Totowa, LLC, designed, researched, tested, and manufactured Digitek® (Digoxin). Mylan Pharmaceuticals, Inc. distributed Digitek® (Digoxin) through its affiliates Mylan Bertek Pharmaceuticals, Inc. and UDL Laboratories, Inc. under the labels of Bertek and UDL. All defendants advertised, marketed, promoted and sold Digitek® (Digoxin).

14. Digitek® (Digoxin) is widely used in the treatment of various heart conditions including atrial fibrillation, atrial flutter and heart failure that cannot be controlled by other medications. The United States Food and Drug Administration approved the medication to be manufactured, distributed and sold with approved levels of active ingredient.

15. Digitek® is approved only for sale and distribution in the United States in the following dosages: (a) Digitek® (Digoxin tablets, USP) 0.125mg, and (b) Digitek® (Digoxin tablets, USP) 0.250 mg.

16. Each Digitek® tablet is approved by the United States Food and Drug Administration ("FDA") only for sale and distribution if it contains the labeled amount of Digoxin.

17. Digitek® (Digoxin) has a narrow therapeutic index, and thus, has a limited margin between effectiveness and toxicity. Ingestion of excess levels of the active ingredient in

Digitek® (Digoxin) beyond the level approved by the FDA can cause death and other health problems.

B. The FDA Warning Letters

18. Upon information and belief, some of the recalled Digitek® (Digoxin) was marketed, designed, developed, manufactured, produced, processed, compounded, formulated, tested, sold, labeled, packaged, dosed, advertised, promoted, supplied, released, and/or distributed from a plant in Little Falls, New Jersey owned by one or more of the Defendants, which was acquired in December 2005 as part of Actavis' acquisition of another company's generic business.

19. On or about August 15, 2006, the FDA issued a letter warning to the Defendants through Defendant Actavis Totowa, LLC for failing to file periodic safety reports at its manufacturing facility in Little Falls, New Jersey ("The August 2006 Warning Letter").

20. The August 2006 Warning Letter is available on the FDA's website at http://www.fda.gov/foi/warning_letters/archive/g6235d.htm.

21. In the August 2006 Warning Letter, the FDA warned Defendants through Actavis Totowa, LLC that it had violated its adverse medical event reporting obligations, marketed drugs without proper clearance and caused at least twenty-six (26) adverse drug experiences (ADEs) by not submitting periodic safety reports.

22. According to the FDA's August 2006 Warning Letter, an FDA inspection in early 2006 revealed that there were six (6) potentially serious and unexpected adverse drug events relating back to 1999 for products, including Digoxin, that were not properly reported to the

agency.

23. The FDA's August 2006 Warning Letter also warned the Defendants through Actavis Totowa, LLC about not properly investigating serious and unexpected ADEs, not adequately reviewing ADE information, failing to develop proper procedures for surveillance, receipt, evaluation and reporting of ADEs and failing to file periodic safety reports which resulted in at least twenty-six (26) unreported ADEs.

24. On or about February 1, 2007, the FDA issued a Revised Warning Letter to the Defendants through Actavis Totowa, LLC ("Revised Warning Letter") citing "significant deviations from the current Good Manufacturing Practice regulations."

25. Defendants' manufacturing, production, testing and inspection processes do not meet the current Good Manufacturing Practice Regulations as defined by the 21 C.F.R. §210 and 21 C.F.R. §211.

26. The FDA's Good Manufacturing Practice regulations describe the methods, controls, equipment, and facilities that must be in place for the manufacture of pharmaceutical products to ensure consumer safety and that the products are consistent with the purported identity, strength, quality, and purity.

27. The Revised Warning Letter is available on the FDA's Website at http://www.fda.gov/foi/warning_letters/archive/g6235d.htm.

28. In the Revised Warning Letter the FDA noted significant deviations from current good manufacturing practice guidelines, resulting in the adulteration of drug products manufactured by the Defendants that were observed by the FDA during an inspection conducted

July 10, 2006 to August 10, 2006.

29. According to the FDA's Revised Warning Letter,

> Significant deficiencies were found in the operations of your firm's quality control unit, and as a result there is no assurance that many drug products manufactured and released into interstate commerce by your firm have the identity, strength, quality and purity that they purport to possess.

30. The deviations from good manufacturing process observed by the FDA were presented to Actavis Totowa, LLC on an FDA-483 (List of Inspections) at the close of the inspection on August 10, 2006.

31. The FDA's Revised Warning Letter cited deficiencies in the operations of the quality control unit, which included instances where the unit failed to adequately investigate and resolve laboratory deviations and out-of-specification test results for drug products. Specifically according to the Revised Warning Letter,

> Our investigators observed numerous instances where the quality control unit failed to adequately investigate and resolve laboratory deviations and out-of-specification test results involving drug products that ultimately were released for distribution into interstate commerce. Additionally, our investigators uncovered out-of-specification test results in laboratory raw data that were not documented in laboratory notebooks, and found that products were released based on retesting without any justification for discarding the initial out-of-specification test results.

32. The FDA Revised Warning Letter stated that the FDA found during its inspection that analysts did not always document the preparation and testing of samples at the time they were done,

> Master and batch production and control records were found to be deficient in that they did not include complete procedures for documenting the collection of samples. Although your firm's procedures require the collection of in-process blend uniformity samples of three times the weight of finished product tablets or

> capsules, master production records do not require, and batch records do not contain, documentation that the samples are being collected accordingly.

33. The FDA also cited a failure to check for accuracy the input and outputs from a system used to run the high-performance liquid chromatography during the analysis of drug products.

34. Other deficiencies cited by the FDA in the Revised Warning Letter include:

(a) a failure of the quality control unit to recognize that some tablets did not meet in-process specifications;

(b) inconsistent documentation in production records of any failure to meet in-process specifications during tablet compression operations and failure to show that process deviations were promptly corrected to avoid releasing out of specification tablets;

(c) a lack of adequate procedures for conducting bulk product holding time studies;

(d) failure to identify and control rejected in-process materials;

(e) not adequately qualifying select equipment; and

(f) failure to establish and follow written procedures for maintaining manufacturing equipment.

35. The FDA gave an example in the Revised Warning Letter that

> Your firm's cleaning validation studies were found to be inadequate and, as a result, there was no assurance that equipment

> is adequately cleaned between the manufacture of different drug products. [21 CFR 211.67(b)]
> For example:
>
> a) Cleaning validation was performed for the process trains without evaluating for sample recovery for numerous products, including: …Digoxin Tablets, USP, 0.25mg.

36. The FDA remained concerned about the Defendants' manufacturing practices,

> we are concerned about the quality of drug products that have been released from your facility under the serious lack of cGMP controls found during the inspection. Your response provides no assurance that the records and conditions of manufacture and testing of each such lot of drug products released and marketed by your firm will be evaluated to assure that the released drug products have their appropriate identity, strength, quality and purity.

37. The FDA gave the Defendants, through Actavis Totowa, LLC, fifteen (15) working days to provide a written listing of all un-expired released lots of finished drug products that are associated with any out-of-specification test results during manufacture and to provide a description of the actions taken to ensure that lots were suitable for release.

C. The Recall

38. On or about April 25, 2008, the FDA announced a Class I Recall of all lots of Bertek and UDL Laboratories Digitek® (Digoxin) ("recalled Digitek® (Digoxin)"). The FDA announcement, available at http://www.fda.gov/medwatch/safety/2008/safety08.htm#Digitek stated:

> Digitek (Digoxin Tablets, USP):
> Audience: Cardiologists, family physicians, pharmacists, other healthcare professionals, patients
>
> [Posted 04/28/2008] Actavis Totowa LLC notified healthcare professionals of a Class I nationwide recall of all strengths of Digitek, a drug used to treat heart failure and abnormal heart rhythms. The products are distributed by Mylan Pharmaceuticals

> Inc., under a "Bertek" label and by UDL Laboratories, Inc. under a "UDL" label- The product is being recalled due to the possibility that tablets with double the appropriate thickness may contain twice the approved level of active ingredient. The existence of double strength tablets poses a risk of digitalis toxicity in patients with renal failure. Digitalis toxicity can cause nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Several reports of illnesses and injuries have been reported. Patients should contact their healthcare professional with questions.
> [April 25, 2008 - Press Release - Actavis Totowa, LLC]

39. According to the FDA definitions page on their website, Class I Recalls are instituted only when "there is a reasonable probability that the use or exposure to a violative product will cause serious adverse health consequences or death."

40. The Recalled Digitek® (Digoxin) is an adulterated drug and its label and packaging are misbranded.

41. Defendants have failed to inform the medical community and the public, including the Plaintiffs:

(a) How many and which lots of Digitek® (Digoxin) contained amounts of unapproved Digoxin;

(b) How long Defendants manufactured and produced the recalled Digitek® (Digoxin) and how long the adulterated drug was supplied, sold, distributed, and released into the stream of commerce;

(c) How many reports of illness and injuries have been received; and

(d) The nature and extent of the reports of illness and injuries that were received.

42. Defendants' failure to provide the medical community, the public, and the Plaintiffs with full, complete and adequate information about recalled Digitek® (Digoxin) is consistent with the safety violations which led the FDA to issue the August 2006 Warning Letter.

43. Examples of Defendants consistent failure to meet the FDA's current Good Manufacturing Practice Regulations include:

(a) deviating, without written justification, from Defendants' own written specifications, test procedures, and laboratory mechanisms, 21 C.F.R. §211.160(a);

(b) failing to establish the accuracy, specificity, and reproducibility of the test methods that Defendants employed, 21 C.F.R. §211.165(d);

(c) maintaining incomplete laboratory records of all testing data, 21 C.F.R. § 211.194(a)(4);

(d) failing to verify the suitability of all testing methods used under actual conditions of use, 21 C.F.R. §211.194(a)(2);

(e) failing to investigate unexplained out-of-specification testing results for drugs, 21 C.F.R. §211.192;

(f) failing to follow Defendants' own written stability testing program, 21 C.F.R. § 211.166(a);

(g) failing to record and justify deviations from Defendants' own written production and process control procedures, 21 C.F.R. §211.100(b)

(h) failing to examine and test samples to ensure that in-process materials conform to their specifications, 21 C.F.R. §211.110(b);

(i) failing to follow Defendant's own written quality control procedures, 21 C.F.R. §211.22(d);

(j) failing to ensure that all data was reviewed and laboratory deviations were fully investigated and resolved prior to the release of drugs into commercial distribution, 21 C.F.R. §211.22(a);

(k) failing to have laboratory controls sufficient to ensure that components, in—process materials, and finished drug products have the appropriate standards of identify, strength, quality, and purity and conform to their written specifications, 21 C.F.R. §211.160(b); and

(l) failing to reject products that do not meet established standards or specifications and any other relevant quality control criteria, 21 C.F.R. §211.165(f).

44. Upon information and belief, the FDA, having been alerted by adverse events, inspected and found serious manufacturing practice, quality assurance and product safety issues with the production of Digitek® (Digoxin) as well as other products produced, manufactured, tested, marketed, distributed and sold or otherwise placed into the stream of commerce by Defendants.

45. After the Class-I recall for all-lots, all-doses of Digitek® (Digoxin) bearing labels of Defendants, upon information and belief, the Defendants' production lines were stopped and

the Little Falls plant was closed.

46. Throughout the above time-line, Defendants have repeatedly emphasized their reputations for quality manufacturing in publically available corporate documents and corporate run websites despite the above information.

47. Defendants under-reported, underestimated and/or downplayed the serious dangers and the defective nature of Digitek® (Digoxin).

48. Defendants have a history of releasing drug products for public consumption that have been adulterated or misbranded.

49. Defendants have a history of failing reliably to establish the identity, strength, quality and purity of drug products they release for public consumption.

50. Defendants have a history of failing adequately to investigate and document test results on their drug products.

51. The Defendants are drug companies, that upon information and belief, engaged in the marketing, design, development, manufacture, production, processing, compounding, formulating, testing, sale, labeling, packaging, dosing, advertising, promotion, supplying, releasing and/or distribution of Digitek® (Digoxin) tablets with amounts of the active ingredient that was not consistent among Digitek® (Digoxin) tablets and amounts of the active ingredient that was inconsistent with the dose on the Digitek® (Digoxin) label.

52. At all times relevant to this action, Defendants knew, and/or had reason to know that the recalled Digitek® (Digoxin) tablets were not safe for the patients for whom the drug was

prescribed because inconsistent or excess does of Digoxin can cause serious medical problems, Digoxin overdose, Digitalis toxicity and, in certain patients, catastrophic injuries and death.

53. Defendants failed to adequately warn users of the defective drug of its unreasonably dangerous characteristics due to the inconsistent and/or excess levels of active ingredient the drug contained.

V. CLAIMS FOR RELIEF

COUNT ONE: PRODUCT LIABILITY – FAILURE TO WARN AND INSTRUCT

54. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

55. At all relevant times hereto, Defendants were engaged in the design, formulation, research, manufacturing, testing, advertising, promoting, marketing, sales and/or distribution of Digitek® (Digoxin). Defendants designed, formulated, manufactured, promoted, marketing, sold and distributed Digitek® (Digoxin), knowing that it would then be prescribed for and ingested by patients with heart disease and disorders.

56. Digitek® (Digoxin) was expected to, and did, reach the usual consumers, handlers and persons coming into contact with said drug without substantial change in the condition in which it was produced, manufactured, tested, labeled, sold, distributed and marketed by Defendants.

57. At all times relevant to this Complaint, Digitek® (Digoxin) was in an unsafe, defective, and inherently dangerous condition which was unreasonably dangerous to its users, because the labeling, packaging, and warnings were insufficient to alert consumers, including the

Plaintiffs, of the dangerous risks and reactions associated with the recalled Digitek® (Digoxin), including but not limited to failure to warn that the amount of active ingredient was not consistent among Digitek® (Digoxin) tablets and the amount of active ingredient was inconsistent with the dose on the Digitek® (Digoxin) label.

58. The pills produced, manufactured, tested, marketed, distributed and sold or otherwise placed into the stream of commerce by Defendants were in a dangerous and defective condition and posed a threat to anyone that ingested the product. Plaintiffs were and are in a class of persons that Defendants should have considered to be subject to the harm caused by the defective nature of Digitek® (Digoxin).

59. Plaintiffs used Digitek® (Digoxin) for the purpose and manner normally intended for the drug. This use has resulted in injury to Plaintiffs.

60. Defendants knew, or should have known, at all times relevant herein, through quality control procedures, testing, adverse event reporting or otherwise that Digitek® (Digoxin) was in a defective condition, was inherently dangerous and unsafe and created a high risk of bodily injury and serious harm.

61. The label, warnings, and dosage information provided with the recalled Digitek® (Digoxin) were not accurate, and the Defendants failed to provide adequate and timely warnings or instructions regarding Digitek® (Digoxin).

62. The Plaintiffs, individually and through their prescribing physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

63. The Defendants had a continuing duty to warn the Plaintiffs of the dangers

associated with the recalled Digitek® (Digoxin).

64. Had the Plaintiffs received adequate information or warnings regarding the dose of Digoxin in the recalled Digitek® (Digoxin) and/or information regarding the risks of ingesting the subject product, they would not have used it.

65. As a direct and proximate result of Defendants' acts and omissions, Plaintiffs have sustained severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT TWO: PRODUCT LIABILITY – MANUFACTURING DEFECT

66. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

67. At all relevant times hereto, Defendants were engaged in the design, formulation, production, research, manufacturing, testing, advertising, promoting, marketing, sale and/or distribution of Digitek® (Digoxin). Defendants designed, formulated, produced, manufactured, promoted, marketed, sold and distributed Digitek® (Digoxin), knowing that it would then be prescribed for and ingested by patients with heart disease and disorders.

68. The manufacturing defects of the recalled Digitek® (Digoxin) occurred while the product was in the possession and control of the Defendants and the recalled Digitek® (Digoxin) was expected to, and did, reach the usual consumers, handlers and persons coming into contact with said drug without substantial change in the condition in which it was produced, manufactured, tested, labeled, sold, distributed and marketed by Defendants.

69. Defendants knew or should have known of the manufacturing defects and the risk of serious bodily injury that exceeded the benefits associated with the recalled Digitek® (Digoxin).

70. Furthermore, the recalled Digitek® (Digoxin) and its defects presented an unreasonably dangerous risk beyond what the ordinary consumer would reasonably expect.

71. At all times relevant to this Complaint, the recalled Digitek® (Digoxin) was not made in accordance with the Defendants' specifications or performance standards and/or those specifications and standards approved by the FDA and was defective because the amount of active ingredient was not consistent among Digitek® (Digoxin) tablets and the amount of active ingredient was inconsistent with the dose on the Digitek® (Digoxin) label.

72. Plaintiffs used Digitek® (Digoxin) for the purpose and manner normally intended for the drug. This use has resulted in injury to Plaintiffs.

73. As a direct and proximate result of Defendants' acts and omissions, Plaintiffs have sustained severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT THREE: PRODUCT LIABILITY –DESIGN DEFECT

74. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

75. At all relevant times hereto, Defendants were engaged in the design, formulation, research, development, manufacturing, testing, production, inspection, packaging, promoting,

marketing, sale and/or distribution of Digitek® (Digoxin). Defendants designed, formulated, manufactured, promoted, marketed, sold and distributed Digitek® (Digoxin), knowing that it would then be prescribed for and ingested by patients with heart disease and disorders.

76. Digitek® (Digoxin) was expected to, and did, reach the usual consumers, handlers and persons coming into contact with said drug without substantial change in the condition in which it was designed, formulated, produced, manufactured, tested, labeled, sold, distributed and marketed by Defendants.

77. Defendants knew or should have known of the design defects and the risk of serious bodily injury that exceeded the benefits associated with the recalled Digitek® (Digoxin).

78. At all times relevant to this Complaint, the recalled Digitek® (Digoxin) was defective in ways which include:

(a) When placed in the stream of commerce, the Recalled Digitek® (Digoxin) contained an unreasonably dangerous design defect and was not reasonably safe as intended to be used, subjecting the Plaintiffs to risks that exceeded the benefits of the Digitek® (Digoxin), including but not limited to serious bodily injuries and even death in an unacceptably high number of its users;

(b) When placed in the stream of commerce, the recalled Digitek® (Digoxin) was defective in design and formulation, making the use of the recalled Digitek® (Digoxin) more dangerous than an ordinary consumer would reasonably expect, and more dangerous than other risks associated with

other digoxin medications and similar drugs on the market, including Digitek® (Digoxin) with doses that were consistent with the dose on the label;

(c) The recalled Digitek® (Digoxin) was insufficiently tested and inspected;

(d) The recalled Digitek® (Digoxin) caused harmful side-effects that outweighed any potential utility; and

(e) The recalled Digitek® (Digoxin) was not accompanied by adequate instructions and/or warnings and labeling to fully apprise consumers, including Plaintiffs, of the full nature and extent of the risks and side-effects associated with its use and that the amount of active ingredient was not consistent among Digitek® (Digoxin) tablets and the amount of active ingredient was inconsistent with the dose on the Digitek® (Digoxin) label.

79. Plaintiffs used Digitek® (Digoxin) for the purpose and manner normally intended for the drug. This use has resulted in injury to Plaintiffs.

80. In addition, at the time the recalled Digitek® (Digoxin) left the control of Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of injury to the Plaintiffs without impairing the reasonably anticipated or intended function of the product. These safer alternative designs, including Digitek® (Digoxin) with a dose of Digoxin consistent with the dose on the label, were economically and technologically feasible, and would have prevented or significantly reduced the risk of injury to Plaintiffs without substantially impairing the product's utility.

81. As a direct and proximate result of Defendants' acts and omissions, Plaintiffs have sustained severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT FOUR: NEGLIGENCE

82. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

83. At all relevant times hereto, Defendants had a duty to Plaintiffs to exercise reasonable care in the design, development, manufacture, production, inspection, testing, labeling, packaging, promotion, marketing, supplying, sale or distribution of recalled Digitek® (Digoxin) for public consumption.

84. Defendants failed to exercise reasonable care and were negligent, reckless, willful, wanton and grossly negligent through the following acts and omissions:

(a) Manufacturing, designing, promoting, formulating, creating, marketing, packaging, distributing and selling Digitek® (Digoxin) in violation of FDA drug approved requirements because the drug was released for public consumption with excess levels of active ingredient beyond that approved by the FDA;

(b) Manufacturing, designing, producing, promoting, formulating, creating, marketing, distributing and selling Digitek® (Digoxin) without properly testing it to ensure it did not have inconsistent or excess levels of active

ingredient;

(c) Manufacturing, designing, producing, promoting, formulating, creating, marketing, distributing and selling Digitek® (Digoxin) in a manner that was dangerous to intended users because it contained inconsistent or excess levels of active ingredient;

(d) Failing to implement a manufacturing process for the drug that satisfied the Food and Drug Administration's manufacturing standards which resulted in unreasonably dangerous manufacturing defects, and then failing to warn of the unreasonable risks created by these manufacturing defects;

(e) Failing to adequately warn, timely recall or otherwise notify health care providers and users at the earliest date that it became known that Digitek® (Digoxin) was dangerous and defective because it contained inconsistent or excess levels of active ingredient;

(f) Negligently advertising and recommending the use of Digitek® (Digoxin) without ensuring the safety of the drug for its intended use;

(g) Failing to reliably establish the identity, strength, quality and purity of the Digitek® (Digoxin) that Defendants released into the market;

(h) Failing to conduct adequate post-marketing surveillance to ensure the safety of Digitek® (Digoxin); and

(i) Failing to systematically monitor usage, clinical experience,

manufacturing quality assurance and adverse event reports on an active basis was negligent breach of the defendants' duty of pharmacovigilence that contributed substantially to causing Plaintiffs' injury.

85. Defendants under-reported, underestimated and/or downplayed the serious dangers and the defective nature of Digitek® (Digoxin).

86. Defendants knew or should have known that consumers such as Plaintiffs would foreseeably suffer injury, including death, as a result of Defendants' failure to exercise ordinary care as outlined above.

87. Defendants' negligence was a proximate cause of Plaintiffs injuries, and the actions and omissions alleged hereinabove arise to the level of reckless, wanton disregard and punitive damages are warranted.

88. As a direct and proximate result of Defendants' negligent, reckless, willful, wanton and grossly negligent acts and omissions, Plaintiffs have sustained severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory, equitable and punitive damages and declaratory relief in an amount to be proven at trial.

COUNT FIVE: NEGLIGENCE *PER SE*

89. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

90. At all times relevant hereto, Defendants had an obligation not to violate the law, in the design, development, formulation, manufacture, production, compounding, testing,

inspecting, processing, assembling, testing, marketing, labeling, packaging, preparing for use, release, sale, distribution and warning of the risk and dangers of Digitek® (Digoxin).

91. At all times relevant to this Complaint, Defendants violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.*, related amendments, codes and federal regulations provided there under, and other applicable laws, statutes, and regulations.

92. Plaintiffs, as the purchasers and consumers of the recalled Digitek® (Digoxin), are within the class of persons the statutes and regulations described above are designed to protect, and the injuries alleged herein are the type of harm these statutes are designed to prevent.

93. Defendants' acts constitute an adulteration and misbranding as defined by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 331, and the regulations promulgated there from and constitutes a breach of duty under the theory of negligence *per se*.

94. Defendants' manufacturing, production, testing and inspection processes are not good manufacturing processes in violation of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 331, and the regulations promulgated there from and constitutes a breach of duty under the theory of negligence *per se.*

95. The acts and omissions set forth above, demonstrate that Defendants failed to meet the standard of care set by the applicable statutes and regulations, which were intended for the benefit of individuals such as Plaintiffs making Defendants negligent *per se.*

96. The actions and omissions alleged hereinabove arise to the level of reckless, wanton disregard and punitive damages are warranted.

97. As a direct and proximate result of Defendants' negligent, reckless, willful, wanton and grossly negligent acts and omissions, Plaintiffs have sustained severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory, equitable and punitive damages and declaratory relief in an amount to be proven at trial.

COUNT SIX: BREACH OF IMPLIED WARRANTY

98. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

99. West Virginia law imposes a duty on the seller of a product to warrant that a product is reasonably fit for its intended purpose.

100. Defendants, as sellers of Digitek® (Digoxin), warranted that the drug was safe for its intended purpose, including the treatment of certain cardiac problems including atrial fibrillation, atrial flutter and heart failure patients who remain symptomatic after attempts at other treatment.

101. Plaintiffs reasonably relied on the belief that Digitek® (Digoxin) was reasonably safe and fit for its intended purpose.

102. Defendants breached this implied warranty because the Digitek® (Digoxin) released for public consumption had amounts of active ingredient that was not consistent among Digitek® (Digoxin) tablets and had amounts of active ingredient that was inconsistent with the dose on the Digitek® (Digoxin) label, and was not of merchantable quality and was not safe or fit for its intended use and purpose.

103. Defendants' breach of this implied warranty was a proximate cause of Plaintiffs injuries as aforesaid.

COUNT SEVEN: BREACH OF EXPRESS WARRANTY

104. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

105. At all relevant times, Defendants expressly warranted that Digitek® (Digoxin) would be reasonably safe and fit for its intended purpose and warranted that it contained a dose of digoxin that was consistent with the dose set forth on its label and was otherwise safe for human ingestion.

106. Plaintiffs reasonably relied on the express warranty of Defendants that Digitek® (Digoxin) was reasonably safe and fit for its intended use.

107. Digitek® (Digoxin) does not conform to the express warranties of Defendants because the drug, as produced for public consumption, is defective and presents a high risk for injury and death to its intended users.

108. Defendants breached their express warranty regarding the safety and fitness of Digitek® (Digoxin).

109. Defendants' breach of their express warranty was a proximate cause of Plaintiffs' injuries including sustained severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT EIGHT: NEGLIGENT MISREPRESENTATION

110. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

111. At the time Defendants manufactured, designed, marketed, sold and distributed Digitek® (Digoxin), Defendants knew or should have known of the uses for which Digitek® (Digoxin) was intended and the serious risks and dangers associated with such of the recalled Digitek® (Digoxin).

112. Defendants owed a duty to treating physicians and ultimate end users of Digitek® (Digoxin), including Plaintiffs, to accurately and truthfully represent the risks of Digitek® (Digoxin). Defendants breached that duty by misrepresenting and/or failing to adequately warn Plaintiffs, the medical community and the public about the risks of Digitek® (Digoxin), which Defendants knew or in the exercise of diligence should have known.

113. Defendants also owed a duty to the physicians and ultimate end users of Digitek® (Digoxin), including Plaintiffs, to conduct appropriate and adequate inspection and tests for all of their products, including the recalled Digitek® (Digoxin), and to use safe and good manufacturing and production practices, to provide appropriate and adequate information and warnings but they failed to do so.

114. Defendants made misrepresentations, without any reasonable grounds for believing their statements to be true, to Plaintiffs, other patients, and the medical community.

115. Defendants, through its misrepresentations, intended to induce justifiable reliance by Plaintiffs, and the medical community.

116. The actions and omissions alleged hereinabove arise to the level of reckless, willful, and wanton disregard and punitive damages are warranted.

117. As a direct and proximate result of Defendants' negligent misrepresentations, the Plaintiffs were injured as aforesaid.

COUNT NINE: INTENTIONAL MISREPRESENTATION

118. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

119. Defendants, having undertaken to prepare, design, research, develop, formulate, manufacture, inspect, test, label, market, promote and sell Digitek® (Digoxin), owed a duty to provide accurate and complete information regarding Digitek® (Digoxin).

120. Defendants misrepresented to Plaintiffs and the medical community the safety and effectiveness of Digitek® (Digoxin) and/or fraudulently, intentionally and/or negligently concealed material information, including adverse information regarding the safety and effectiveness of Digitek® (Digoxin) and the dose of digoxin contained therein.

121. Defendants made misrepresentations and actively concealed adverse information at a time when the Defendants knew, or should have known, that Digitek® (Digoxin) had defects, dangers and characteristics that were other than what the Defendants had presented to Plaintiffs, the public, the FDA and the medical community generally. Specifically, Defendants misrepresented to Plaintiffs, the public, the FDA, and the medical community that:

(a) The dose of the active ingredient digoxin was consistent between Digitek® (Digoxin) tablets;

(b) The dose of the active ingredient digoxin was a dose that was approved by the FDA;

(c) The dose of the active ingredient digoxin was what the label represented the dose to be; and/or

(d) Digitek® (Digoxin) had been tested and was found to be safe and/or effective for use.

122. The representations made by Defendants were, in fact, false.

123. Defendants engaged in all the acts and omissions described above with the intent that Plaintiffs' physicians, Plaintiffs and the medical community in general would rely on the misrepresentation, deception and concealment in deciding to prescribe, recommend, dispense and/or purchase Digitek® (Digoxin).

124. Plaintiffs, Plaintiffs' treating physicians, healthcare providers and/or hospitals justifiably relied to their detriment on Defendants' intentional and fraudulent misrepresentations. This reliance proximately caused Plaintiffs' injuries.

125. The actions and omissions alleged hereinabove arise to the level of reckless, willful, wanton, intentional and fraudulent disregard and punitive damages are warranted.

126. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT TEN: FRAUD

127. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

128. At all relevant times during the course of dealing between Defendants and Plaintiffs and/or Plaintiffs' physicians, Defendants represented its Digitek product to be safe and effective, and omitted, misrepresented, concealed and suppressed that Digitek® (Digoxin) was not safe or effective for its intended use.

129. In representations to Plaintiffs, Plaintiffs' physicians and the medical community in general, Defendants fraudulently concealed the following material information:

(a) That for several years, Defendants knew or had reason to know of problems with its' manufacturing process and that Digitek® (Digoxin) was negligently manufactured;

(b) That Digitek® (Digoxin) was defective and that the amount of active ingredient was not consistent among Digitek® (Digoxin) tablets and the amount of active ingredient was inconsistent with the dose on the Digitek® (Digoxin) label;

(c) That the risk of adverse events with the defective Digitek® (Digoxin) was not adequately tested for and/or known by Defendants;

(d) That Defendants were aware of complaints regarding adverse side effects since 2006 and did nothing.

130. Defendants were under a duty to disclose to Plaintiffs, the medical community,

and public, the defective nature of Digitek® (Digoxin), and had full access to material facts concerning the defective nature of Digitek® (Digoxin).

131. Defendants intentionally, knowingly, and/or recklessly misrepresented that Digitek® (Digoxin) was safe and effective for its intended use.

132. Defendants' misrepresentations, concealment, suppression and omissions were made purposefully, willfully, wantonly, uniformly, deliberately or recklessly to Plaintiffs, the medical community, and the public, to induce the recommendation, dispense, purchase and use of Digitek® (Digoxin) over the other products available on the market.

133. Plaintiffs, Plaintiffs' physicians, healthcare providers and/or hospitals reasonably and justifiably relied upon the misrepresentations and omissions made by the Defendants about Digitek® (Digoxin) when agreeing to recommend, dispense, purchase and/or use Digitek® (Digoxin).

134. Defendants knew that Plaintiffs had no way to determine that the Defendants' misrepresentations about Digitek® (Digoxin) were false and misleading, and that they included material omissions.

135. The intentional, wanton, reckless, unlawful, malicious, and fraudulent actions and omissions alleged hereinabove arise to the level of reckless, wanton disregard and punitive damages are warranted.

136. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory, equitable and

punitive damages and declaratory relief in an amount to be proven at trial.

COUNT ELEVEN: CONSTRUCTIVE FRAUD

137. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

138. At the time Defendants designed, formulated, manufactured, promoted, marketed, sold and distributed Digitek® (Digoxin), Defendants were in a unique position of knowledge concerning the safety and effectiveness of Digitek® (Digoxin), which knowledge was not possessed by Plaintiffs, their physicians, or healthcare providers, and Defendants thereby held a position of superiority over Plaintiffs.

139. Through their unique knowledge and expertise regarding the defective Digitek® (Digoxin), and through their statements to Plaintiffs, Plaintiffs' physicians, and healthcare providers in advertisements, promotional materials, labels, packaging, and other communications, Defendants professed to Plaintiffs that they had knowledge of the truth of the representation that Digitek® (Digoxin) was safe and effective for its intended use and was not defective.

140. Defendants' representations to Plaintiffs, the medical community, and the public were unqualified statements made to induce Plaintiffs, Plaintiffs' physicians and healthcare providers to recommend, dispense, purchase and use Digitek® (Digoxin), and Plaintiffs relied upon these statements when purchasing and/or using Digitek® (Digoxin).

141. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiffs and engaged in constructive fraud in their relationship with

Plaintiffs. Plaintiffs reasonably relied on Defendants' representations.

142. The actions and omissions alleged hereinabove arise to the level of reckless, willful and wanton disregard and punitive damages are warranted.

143. As a direct and proximate result of Defendants' reckless, willful, wanton, grossly negligent and wrongful conduct, Plaintiffs have sustained severe physical injuries and/or death, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory, equitable and punitive damages and declaratory relief in an amount to be proven at trial.

COUNT TWELVE: VIOLATION OF WEST VIRGINIA CONSUMER CREDIT AND PROTECTION ACT (WEST VIRGINIA CODE § 46A-6-101, ET SEQ.)

144. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

145. Defendants engaged in commercial conduct by selling Digitek® (Digoxin).

146. Defendants misrepresented and omitted material information regarding Digitek® (Digoxin) by failing to disclose known risks and had Plaintiffs' known of such risks, they would not have purchased the drug.

147. Defendants' misrepresentations and concealment of material facts constituted unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation and/or the knowing concealment, suppression, or omission in connection with the sale and advertisement of Digitek® (Digoxin) in violation of the West Virginia Consumer Credit and Protection Act, W.Va. Code §§ 46A-6-101, *et seq.*

148. The West Virginia Consumer Credit and Protection Act was enacted to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. Defendants violated these statutes by knowingly and falsely representing that Digitek® (Digoxin) was fit to be used for the purpose for which it was intended, when Defendants knew it was defective, dangerous, ineffective, and unsafe, and by other acts alleged herein.

149. Defendants engaged in such deceptive acts and practices alleged herein in order to sell Digitek® (Digoxin) to the public, including Plaintiffs.

150. As a direct and proximate result of Defendants' violations of the West Virginia Consumer Credit and Protection Act, the Plaintiffs suffered economic losses including prescription costs, costs to obtain new prescriptions and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT THIRTEEN: VIOLATION OF APPLICABLE CONSUMER PROTECTION AND/OR UNFAIR TRADE PRACTICES STATUTES

151. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

152. Every State has enacted statutes to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. Defendants violated these statutes by knowing and falsely representing that Digitek® (Digoxin) was fit to be used for the purpose for which it was intended, when Defendants knew it was defective, dangerous, ineffective, unsafe and by other acts alleged herein.

153. Plaintiffs hereby affirm that in the event that jurisdiction and choice of law principles indicate that the consumer protection and unfair trade practices laws of another jurisdiction should be applied on behalf the plaintiff, Plaintiff hereby asserts that:

(a) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ala. Code § 8-19-1, *et seq.*;

(b) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Alaska Stat. § 45.50.471, *et seq.*;

(c) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ariz. Rev. Stat. § 44-1522, *et seq.*;

(d) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ark. Code § 4-88-101, *et seq.;*

(e) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Cal. Civ. Code §1770, *et seq*. and Ca1.Bus. & Prof Code § 17200, *et seq.*;

(f) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or has made false representations in violation of Colo. Rev. Stat. § 6-1-105, *et seq*. and Colo. Rev. Stat. § 6-1-113;

(g) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Conn. Gen. Stat. § 42-110a, *et seq*;

(h) Defendants have engaged in unfair competition or unfair or deceptive acts

or practices in violation of 6 Del. Code §§ 2511, *et seq*. and 2531, *et seq*.;

(i) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of D.C. Code § 28-3901, *et seq*.;

(j) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Fla. Stat. § 501.201, *et seq*.;

(k) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ga. Stat. §§10-1-372, *et seq*., 10-1-392 and 10-1-420.;

(l) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Haw. Rev. Stat. § 480-1, *et seq*.;

(m) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Idaho Code § 48-601, *et seq*.;

(n) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 815 ILCS § 505/1, *et seq*. and 815 ILCS § 510/1 *et seq*.;

(o) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ind. Code Ann. § 24-5-0.5-1, *et seq*.;

(p) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Iowa Code § 714.16, *et seq*.;

(q) Defendants have engaged in unfair competition or unfair or deceptive acts

or practices in violation of Kan. Stat. § 50-623, *et seq.*;

(r) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ky. Rev. Stat. § 367.170, *et seq.*;

(s) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of La. Rev. Stat. § 51:1401, *et seq.*;

(t) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 5 Me. Rev. Stat. § 205A, *et seq.*;

(u) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Md. Com. Law Code § 13-101, *et seq.*;

(v) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mass. Gen. L. Ch. 93A, *et seq.*;

(w) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mich. Comp. Laws Ann. § 445.901, *et seq.*;

(x) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Minn. Stat. §§ 325D.43, *et seq.*, 325F.67, *et seq.*, 325F.68 *et seq.* and 325F.71 *et seq.*;

(y) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Miss. Code Ann. § 75-24-1, *et seq.*;

(z) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Vernon's Ann. Missouri Stat. § 407.010, *et seq.*;

(aa) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Mont. Code Ann. § 30-14-101, *et seq.*;

(bb) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Neb. Rev. Stat. § 59-1601, *et seq.*;

(cc) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Nev. Rev. Stat. Ann. § 598.0903, *et seq.*;

(dd) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.H. Rev. Stat. § 358-A:1, *et seq.*;

(ee) Defendants have engaged in unfair competition or unfair, unconscionable or deceptive acts or practices in violation of N.J. Rev. Stat. § 56:8-1, *et seq.*;

(ff) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.M. Stat. § 57-12-1, *et seq.*;

(gg) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.Y. Gen. Bus. Law §§ 349, *et seq.*;

(hh) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.C. Gen. Stat. § 75-1.1, *et seq.*;

(ii) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of N.D. Cent. Code §§ 51-12-01, *et seq.*, and 51-15-01, *et seq.*;

(jj) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Ohio Rev. Stat. §§ 1345.01, *et seq*. and 4165.01, *et seq*.;

(kk) Defendants have engaged in unfair competition or unfair or deceptive acts or practices or made false representations in violation of Okla. Stat. 15 § 751, *et seq*.;

(ll) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Or. Rev. Stat. § 646.605, *et seq*.;

(mm) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 73 Pa. Stat. § 201-1, *et seq*.;

(nn) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of R.I. Gen. Laws. § 6-13.1-1, *et seq*.;

(oo) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.C. Code Laws § 39-5-10, *et seq*.;

(pp) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of S.D. Codified Laws § 37-24-1, *et seq*.;

(qq) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tenn. Code § 47-18-101, *et seq*.;

(rr) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Tex. Bus. & Com. Code § 17.41, *et seq*.;

(ss) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Utah Code. § 13-11-1, *et seq*.;

(tt) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of 9 Vt. § 2451, *et seq*.;

(uu) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Va. Code § 59.1-196, *et seq*.;

(vv) Defendants have engaged in unfair competition or unfair, deceptive or fraudulent acts or practices in violation of Wash. Rev. Code. § 19.86.010, *et seq*.;

(ww) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of West Virginia Code § 46A-6-101, *et seq*.;

(xx) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wis. Stat. § 100.20, *et seq*.; and

(yy) Defendants have engaged in unfair competition or unfair or deceptive acts or practices in violation of Wyo. Stat. § 40-12-101, *et seq*.

154. As a direct and proximate result of Defendants' negligent, reckless, willful, wanton, and grossly negligent violations of the above Consumer Protection and Unfair Trade Practices Statutes, the Plaintiffs suffered economic losses including prescription costs, costs to obtain new prescriptions and other damages for which they are entitled to compensatory, equitable and punitive damages and declaratory relief in an amount to be proven at trial.

COUNT FOURTEEN: WRONGFUL DEATH

155. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

156. Decedent Plaintiffs died as a direct and proximate result of defects in Defendants' product Digitek® (Digoxin) and are survived by various family members, named and unnamed.

157. Defendants' wrongful conduct has proximately caused Decedent Plaintiffs' heirs and beneficiaries to suffer the loss of Decedents' support, companionship, services, society, marital association, love and consortium.

158. Plaintiff is the personal representative of Decedent Plaintiff, and brings herein this wrongful death claim pursuant to W.Va. Code § 55-7-5, *et seq.* for all damages and claims authorized herein.

159. The actions and omissions alleged hereinabove arise to the level of negligent, grossly negligent, willful, wanton and reckless disregard and punitive damages are warranted.

COUNT FIFTEEN: SURVIVAL ACTION

160. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

161. As a direct and proximate result of the conduct of Defendants outlined above, Decedent Plaintiffs suffered bodily injury and resulting pain and suffering, disability, disfigurement, mental anguish, loss of capacity of the enjoyment of life, shortened life expectancy, and expenses of hospitalization, medical and nursing care and treatment, monitoring, and loss of earnings as well as loss of ability to earn money and other economic damages prior to

Decedents Plaintiffs' death.

162. Plaintiff is the personal representative of Decedent, and brings herein this survival action pursuant to W.Va. Code § 55-7-8 and W.Va. Code § 55-7-8(a) for all damages and claims authorized herein.

163. The actions and omissions alleged hereinabove arise to the level of negligent, grossly negligent, willful, wanton and reckless disregard and punitive damages are warranted.

COUNT SIXTEEN: MEDICAL MONITORING

164. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

165. As a direct result of Defendants' actions, omissions and negligence, Plaintiffs have been put at a heightened risk of very serious health complications. This risk of death and serious health complications requires diagnostic medical examinations. By monitoring and testing the affected Plaintiffs, it can be determined whether they are prone to death and serious health complications as a result of the damages caused by Defendants. Through such testing and monitoring, lives can be saved.

166. Because the ingestion of this defectively manufactured drug poses significant health risks to Plaintiffs, medical monitoring is the most appropriate method by which it can be determined whether a particular Plaintiff should be promptly treated.

167. Accordingly, Defendants should be required to establish a medical monitoring program.

168. Plaintiffs have no adequate remedy at law in that monetary damages alone cannot compensate them for the risk of a fatal cardiac event. Without a Court-approved medical monitoring program, Plaintiffs will continue to face unreasonable risk of death.

COUNT SEVENTEEN: UNJUST ENRICHMENT

169. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

170. As the intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from Plaintiffs purchase of Digitek® (Digoxin).

171. Defendants have voluntarily accepted and retained these profits and benefits, derived from the Plaintiffs, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiffs were not receiving a product of the quality, nature or fitness that had been represented by Defendants, or that Plaintiffs, as reasonable consumers expected.

172. It would be inequitable for Defendants to retain the profits and benefits from Digitek® (Digoxin) because Plaintiffs did not receive a safe and effective drug.

173. By virtue of the conscious wrongdoing alleged above, Defendants have been unjustly enriched at the expense of the Plaintiffs, who are entitled to in equity, and hereby seek, the disgorgement and restitution of Defendants' wrongful profits, revenues and benefits, to the extent and in the amount deemed appropriate by the Court; and such other relief as the Court deems just and proper to remedy the Defendants' unjust enrichment.

COUNT EIGHTEEN: MEDICARE SECONDARY PAYER ACT

174. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

175. In addition to their own personal injury claims, Plaintiffs, whose medical care costs arising from Digitek® (Digoxin) were paid in whole or in party by Medicare, bring this cause of action pursuant to the private cause of action provisions of the Medicare as Secondary Payer Statute [42 U.S.C. § 1395y(b)(3)(A)] to recover "double damages" of all Medicare expenditures resulting from their injuries suffered in connection with the recalled Digitek® (Digoxin).

COUNT NINETEEN: LOSS OF CONSORTIUM

176. Plaintiffs hereby incorporate by reference all preceding paragraphs as if fully set forth herein.

177. At all relevant times hereto, the Plaintiffs had spouses (hereafter referred to as "Spouse Plaintiffs") and/or family members (hereafter referred to as "Family Member Plaintiffs") who have suffered injuries and losses as a result of Plaintiffs' injuries.

178. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have necessarily paid and have become liable to pay for medical aid, treatment, monitoring, medications, and other expenditures and will necessarily incur further expenses of a similar nature in the future as a proximate result of Defendants' misconduct.

179. For the reasons set forth herein, Spouse Plaintiffs and/or Family Member Plaintiffs have suffered and will continue to suffer the loss of their loved one's support,

companionship, services, society, love and affection.

180. For all Spouse Plaintiffs, Plaintiff alleges his/her marital relationship has been impaired and depreciated, and the marital association between husband and wife has been altered.

181. Spouse Plaintiffs and/or Family Member Plaintiffs have suffered great emotional pain and mental anguish.

182. As a direct and proximate result of Defendants' wrongful conduct, Spouse Plaintiffs and/or Family Member Plaintiffs have sustained severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages for which they are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff(s) seeks judgment favor against Defendant(s) as follows:

1. Economic and non-economic damages in an amount in excess of $75,000 as provided by law and to be supported by the evidence at trial;

2. For the equitable relief requested;

3. For compensatory damages according to proof;

4. For punitive damages;

5. For all applicable statutory damages under the Medicare Secondary Payer Act and the applicable consumer protection legislation;

6. For declaratory judgment that Defendant(s) is/are liable to Plaintiff(s) for all evaluative, monitoring, diagnostic, preventative, and corrective medical, surgical, and incidental

expenses, costs and losses caused by Defendants' wrongdoing;

7. For disgorgement of profits;

8. For an award of attorneys' fees and costs;

9. For prejudgment interest and the costs of suit; and

10. For such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff(s) hereby demand a trial by jury as to all claims in this action.

Dated: _____

Respectfully submitted,

On Behalf of the Plaintiffs' Steering Committee

s/Carl N. Frankovitch, Esq._____
Carl N. Frankovitch, Esq.
Frankovitch, Anetakis, Colantonio & Simon
337 Penco Road
Weirton, WV 26062
Co- Lead Counsel

Fred Thompson, III, Esq.
Motley Rice, LLC
28 Bridgeside Blvd.
Mt. Pleasant, SC 29464
Co- Lead Counsel

Harry F. Bell, Jr., Esq.
Bell & Bands PLLC
P. O. Box 1723
Charleston 25326
Liaison Counsel

Teresa Toriseva, Esq.
Toriseva Law
1446 National Road
Wheeling, WV 26003
Chair of Plaintiff Steering Committee

PLAINTIFFS' STEERING COMMITTEE:

Andres F. Alonso, Esq.
Parker, Waichman, Alonso LLP
111 Great Neck Road
Great Neck, New York 11021

K. Camp Bailey, Esq.
Bailey Perrin Bailey
Suite 2100
440 Louisiana Street
Houston, TX 77002-4206

Harry F. Bell, Jr., Esq.
Bell & Bands PLLC
P. O. Box 1723
Charleston, West Virginia 25326

Robert J. Binstock, Esq.
Reich & Binstock
Suite 1000
4265 San Felipe
Houston, TX 77027

Robert Blanchard, Esq.
Levin, Papantonio, Thomas,
Mitchell, Echsner & Proctor, P.A.
316 South Baylen Street, Suite 600
Pensacola, FL 32502

Lester L. Levy, Esq.
Wolf Popper LLP
845 Third Avenue
New York, NY 10022

Peter A. Miller, Esq.
The Miller Firm LLC
The Sherman Bldg.
108 Railroad Avenue
Orange, VA 22960

Ashley L. Ownby, Esq.
180 North Ocoee Street
P. O. Box 176
Chattanooga, TN 37364-0176

David M. Peterson, Esq.
Peterson & Associates, P.C.
Park Plaza Building, Suite 107
801 West 47th Street
Kansas City, MO 64112-1253

Frank Mario Pitre, Esq.
Cotchett, Pitre & McCarthy
Suite 200
840 Malcolm Road
Burlingame, CA 94010

Frank Mario Pitre, Esq.
Cotchett, Pitre & McCarthy
Suite 200
840 Malcolm Road
Burlingame, CA 94010

Ed Blizzard, Esq.
Blizzard, McCarthy & Nabers LLC
Suite 1710
440 Louisiana
Houston, TX 77002

John R. Climaco, Esq.
Climaco, Lefkowitz, Peca, Wilxcox
& Garofoli Co., LPA
55 Public Square, Suite 1950
Cleveland, OH 44113

C. Brooks Cutter, Esq.
Kershaw, Cutter & Ratinoff LLP
401 Watt Avenue
Sacramento, CA 95864

Carl N. Frankovitch, Esq.
Frankovitch, Anetakis, Colantonio & Simon
337 Penco Road
Weirton, WV 26062

Daniel N. Gallucci, Esq.
RodaNast, P.C.
801 Estelle Drive
Lancaster, PA 17601

G. Erick Rosemond, Esq.
Hissey Kientz, L.L.P
9442 Capital of Texas Highway N.
Suite 400
Austin, TX 78759

Shelly A. Sanford, Esq.
Sanford Pinedo LLP
2016 Bissonnet Street
Houston, TX 77005-1647

J. Paul Sizemore, Esq.
Giardi Keese
1126 Wilshire Boulevard
Los Angeles, CA 90017

Fred Thompson, III, Esq.
Motley Rice, LLC
28 Bridgeside Blvd.
Mt. Pleasant, SC 29464

Teresa Toriseva, Esq.
Toriseva Law
1446 National Road
Wheeling, WV 26003

Stacy K Hauer, Esq.
Zimmerman Reed
651 Nicollet Mall, Suite 501
Minneapolis , MN 55402-4123

Scott Wm. Weinstein, Esq.
Morgan & Morgan, P.A.
Suite 600
12800 University Drive
P. O. Box 9504
Fort Myers, FL 33906